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George et al.

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(54) **ELASTIC MEMBER CLAMPS**

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(52) **U.S. Cl.**

CPC **A61B 17/7041** (2013.01); **A61B 17/7053** (2013.01); **A61B 17/7086** (2013.01); **A61B 17/8869** (2013.01)

(58) **Field of Classification Search**

USPC 606/276, 86 A
See application file for complete search history.

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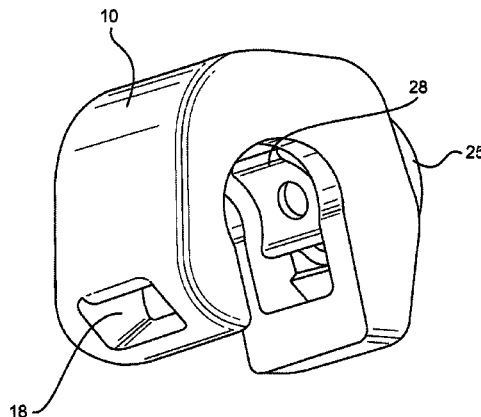
Primary Examiner — Jan Christopher Merene

(57)

ABSTRACT

The present application generally relates to orthopedic stabilization systems, and in particular, to systems including clamps. The clamps can be used in addition to or to replace hooks that grasp onto bone members, such as the lamina. One example of such a clamp is an in-line clamp that includes a central opening for receiving a rod member, a first opening for receiving a set screw and a second opening for receiving an elastic member therethrough. Another example of such a clamp is an off-set clamp that includes an upper plate, a bottom plate, and an opening for receiving a rod therein. The upper plate can be separated from the bottom plate to make space for an elastic member that can be secured within the plates. Tulip clamps that utilize one or more elastic members are also provided.

19 Claims, 14 Drawing Sheets



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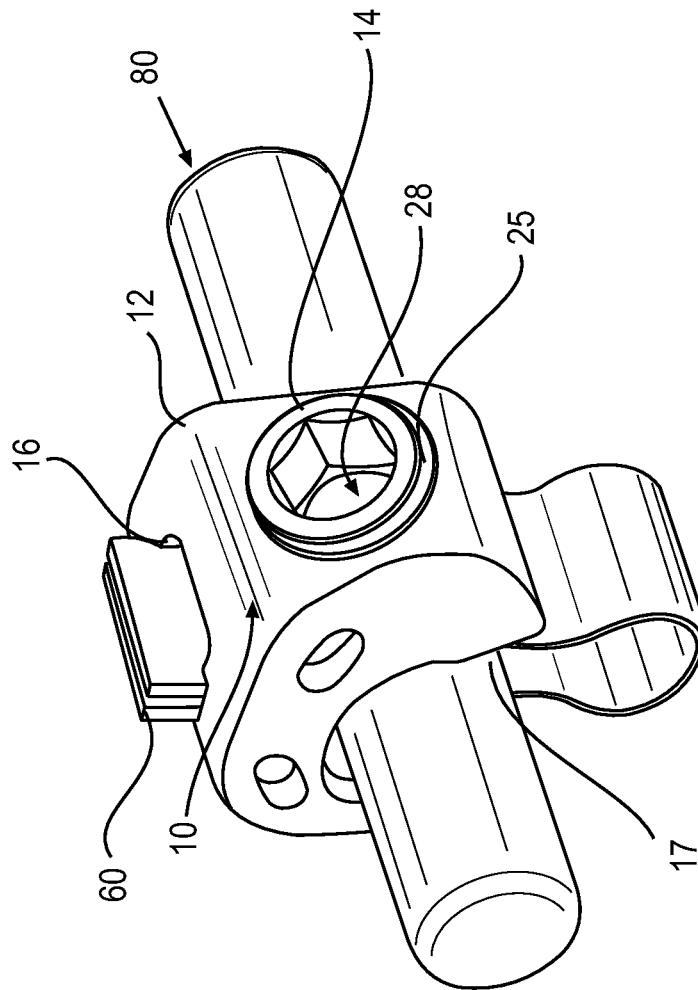


FIG. 1A

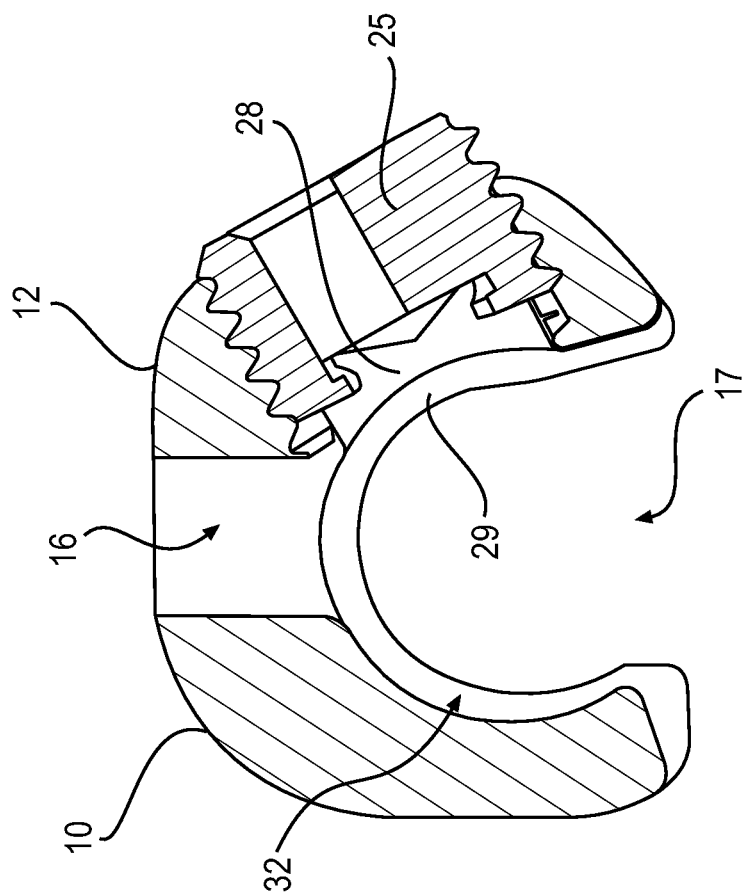
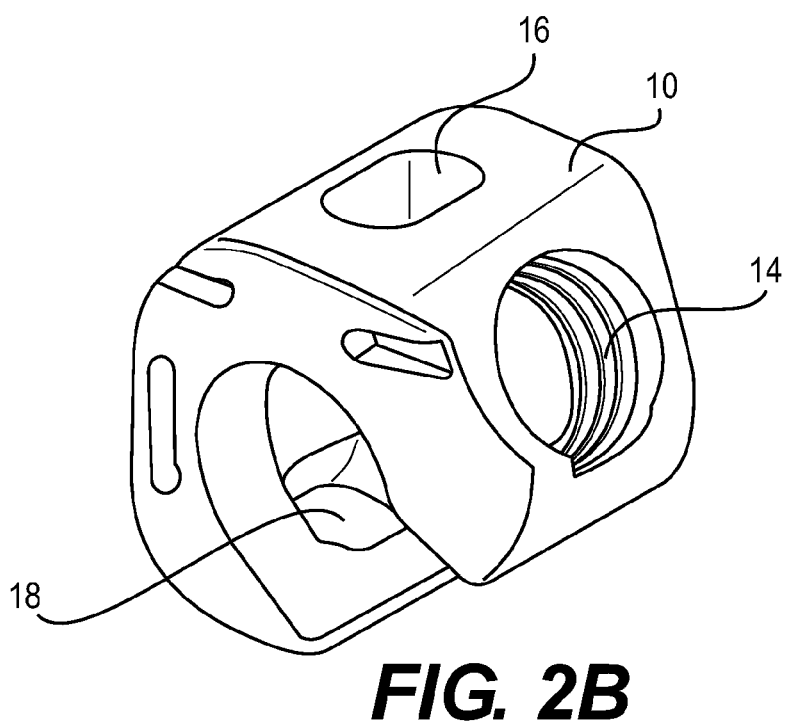
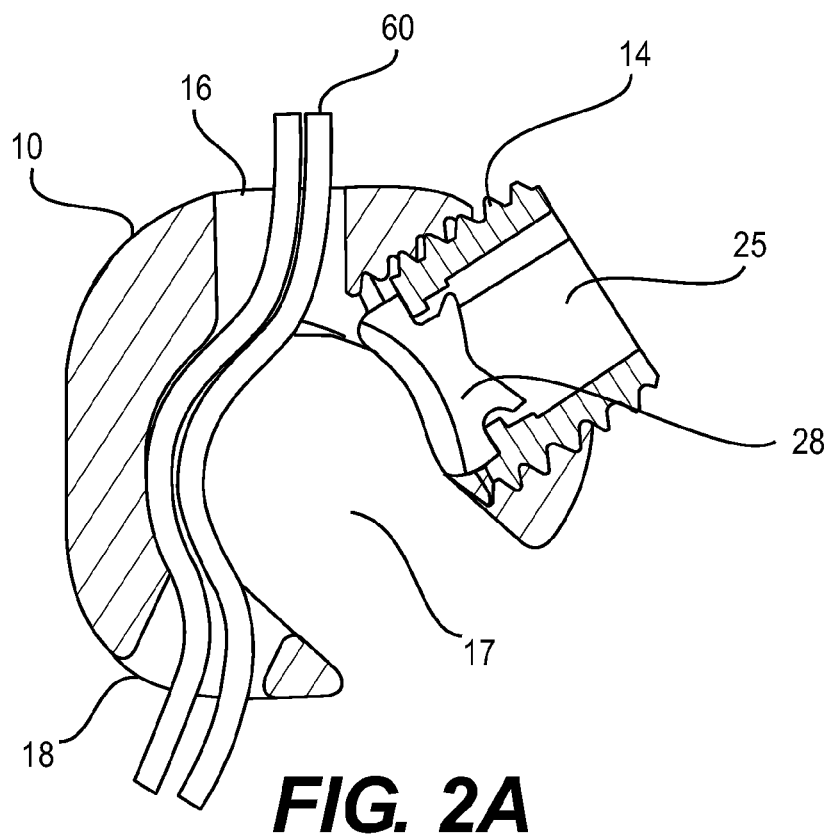


FIG. 1B



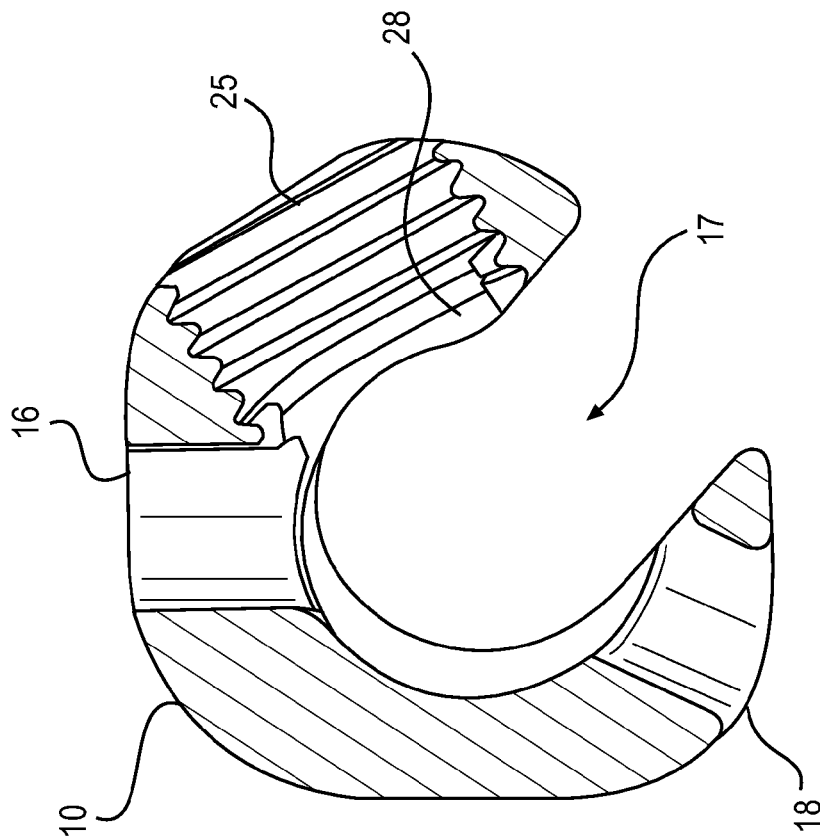


FIG. 2C

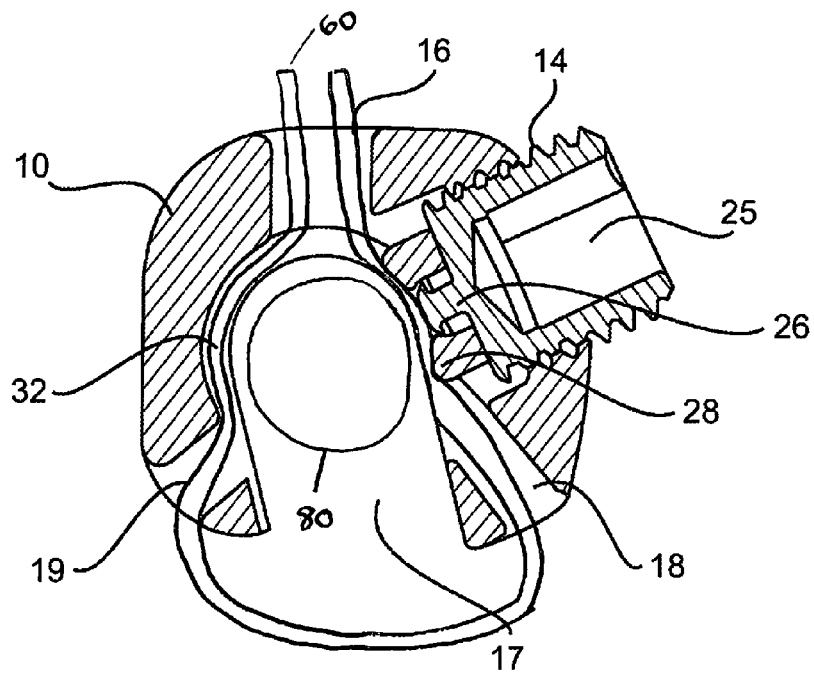


FIG. 3A

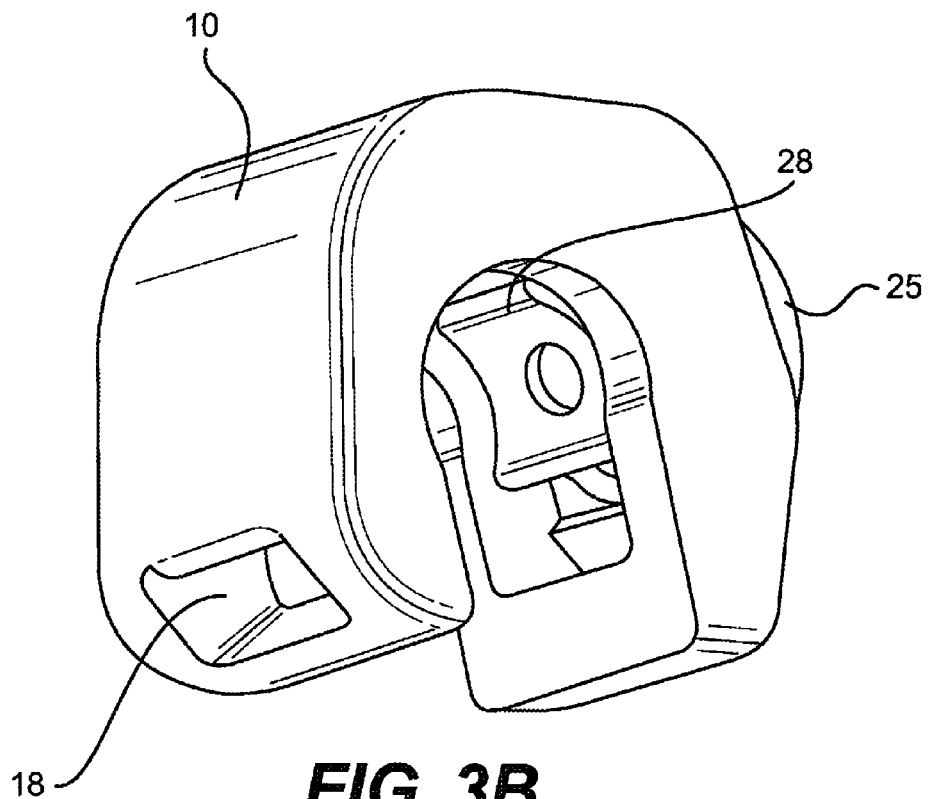
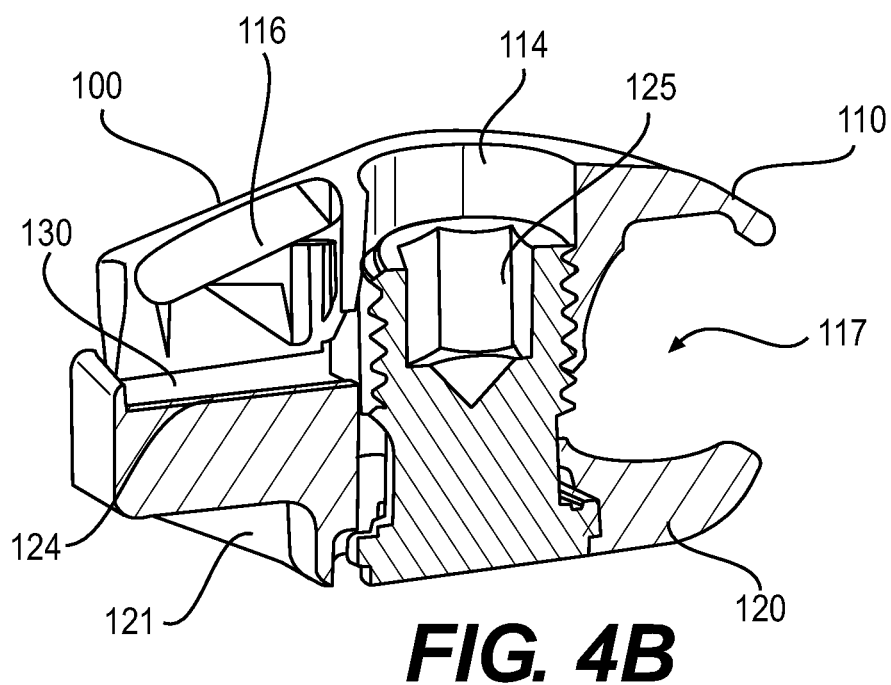
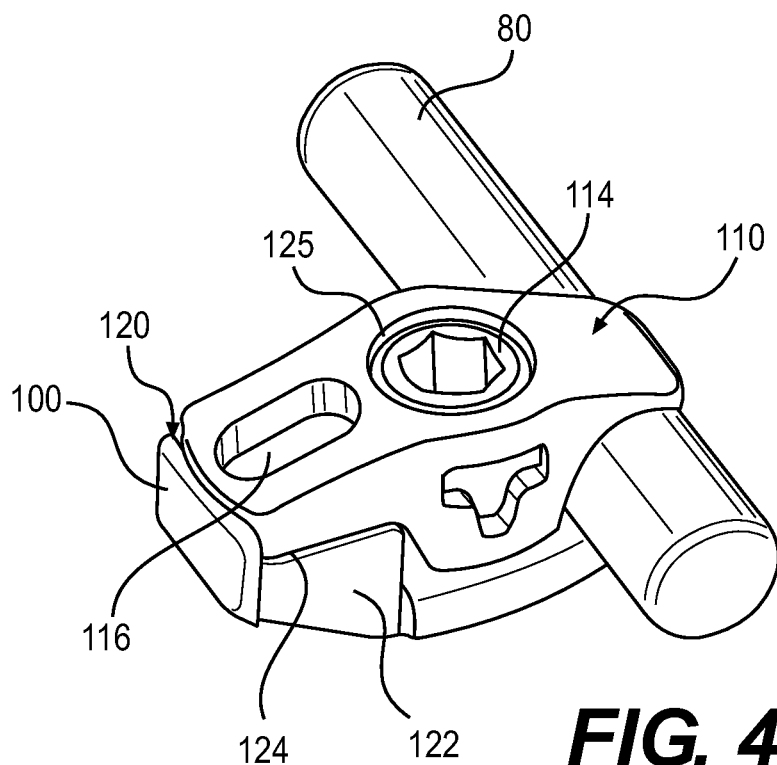


FIG. 3B



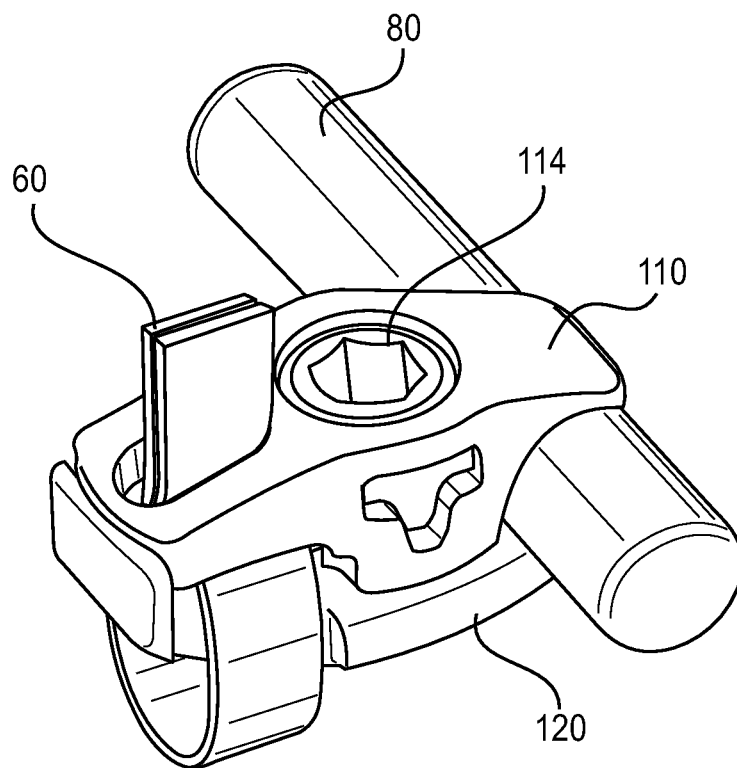


FIG. 4C

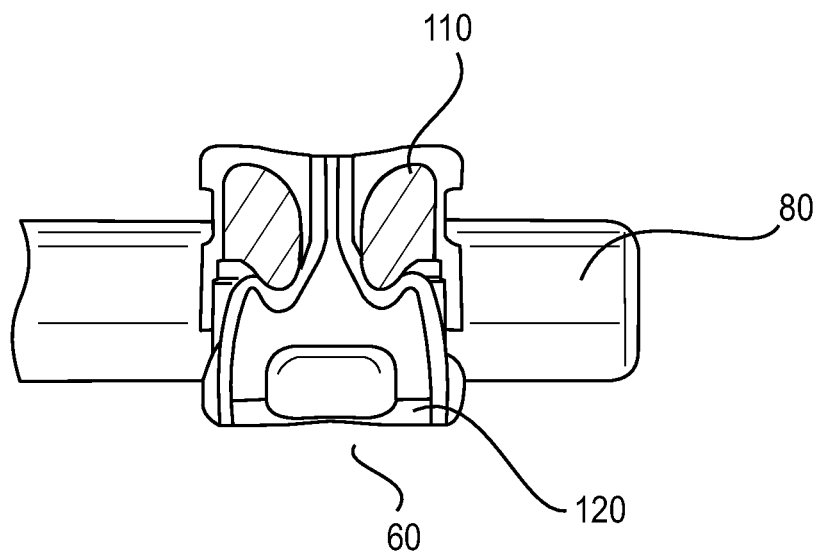
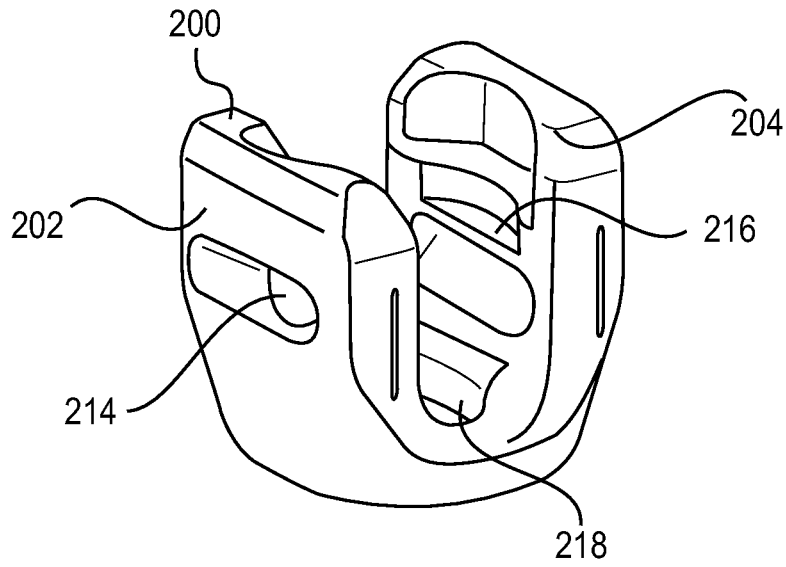
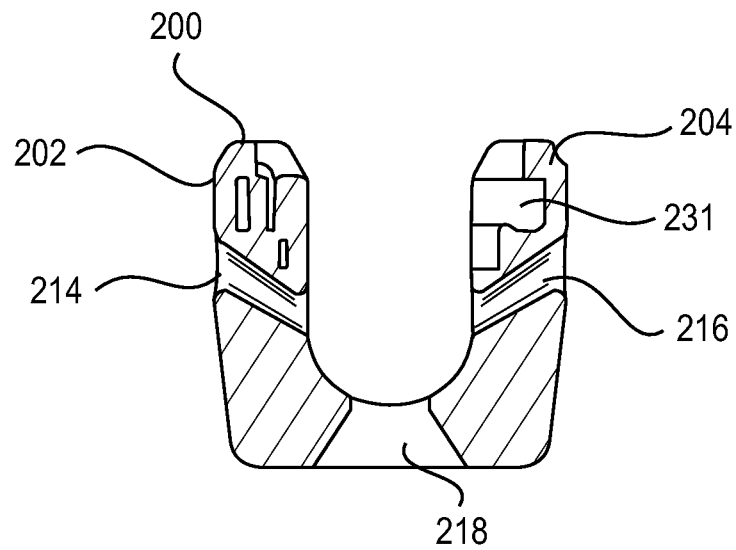
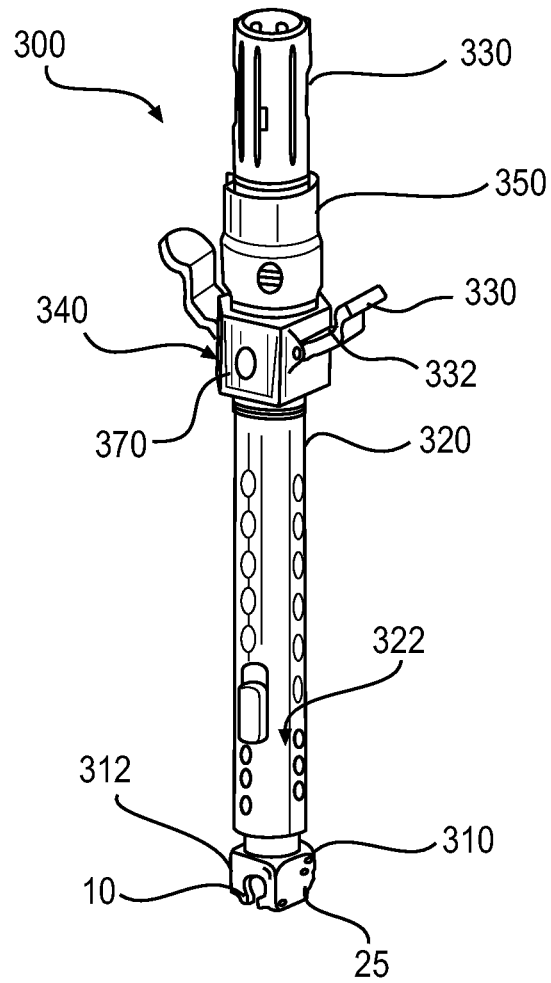
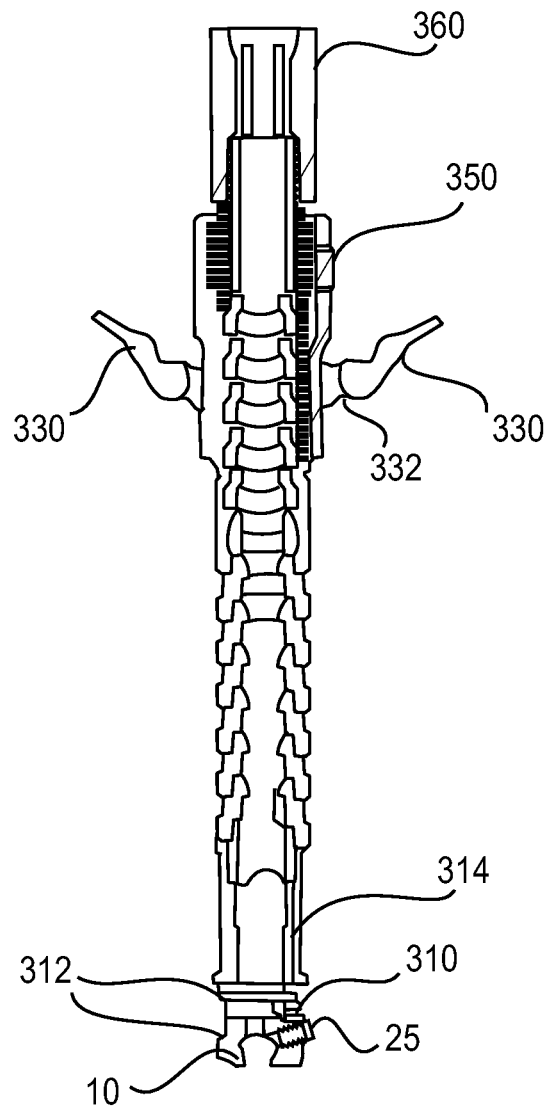


FIG. 4D

**FIG. 5A****FIG. 5B**

**FIG. 6**

**FIG. 7**

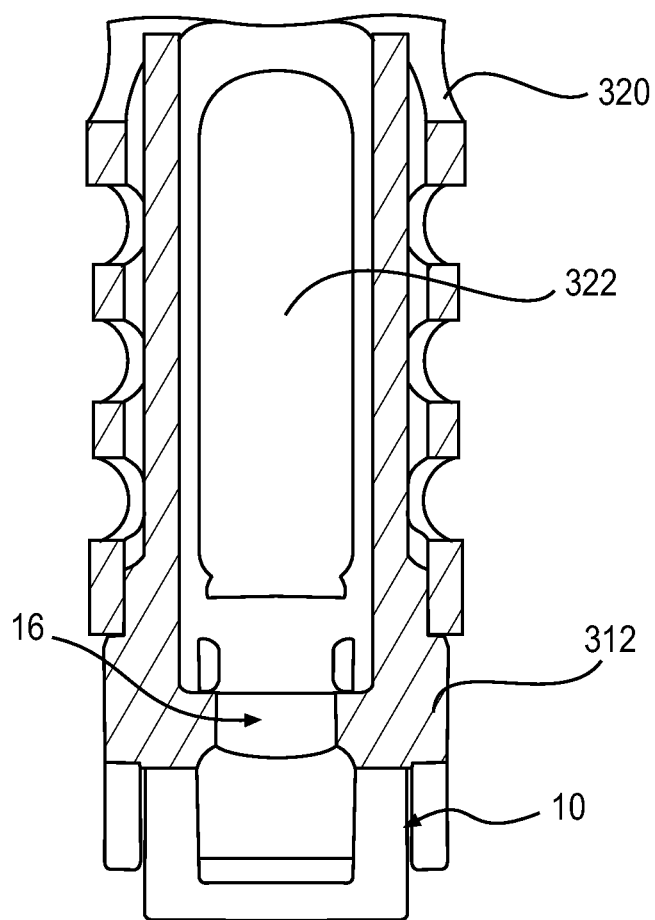


FIG. 8

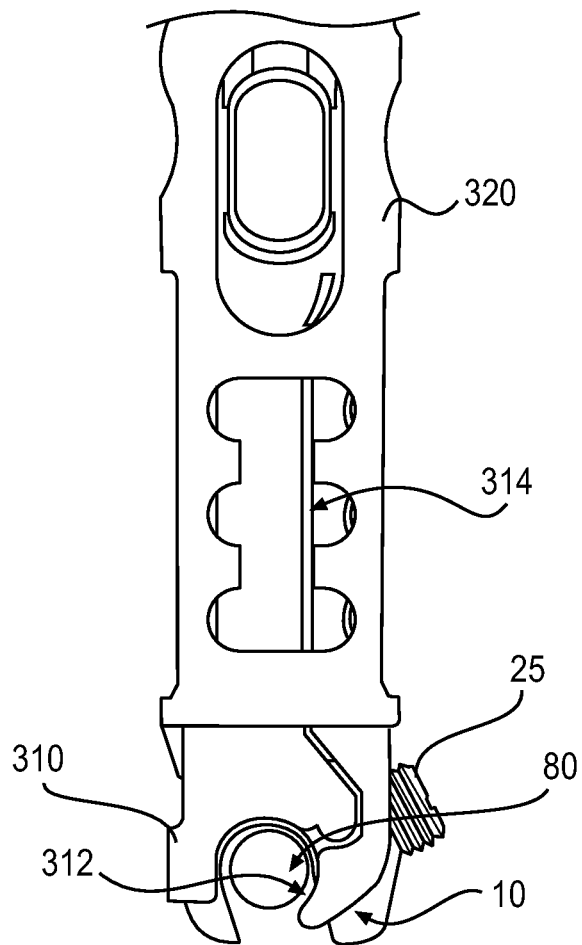


FIG. 9

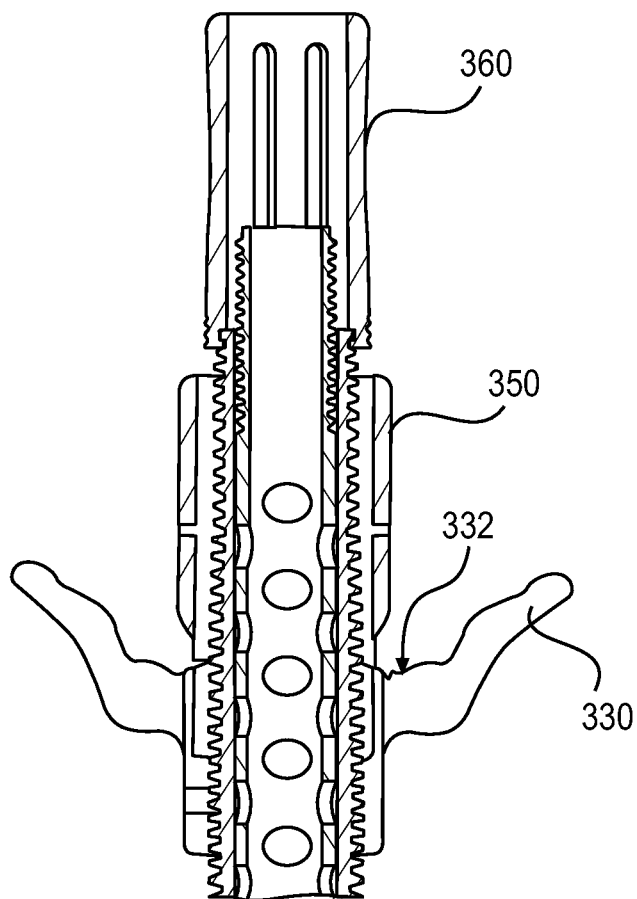


FIG. 10

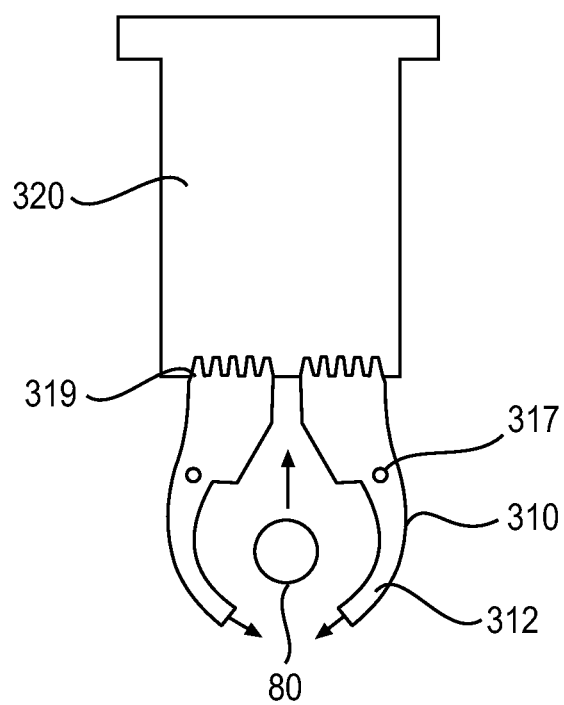


FIG. 11

ELASTIC MEMBER CLAMPS

REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part application of U.S. patent application Ser. No. 13/785,487, filed Mar. 5, 2013, and entitled Elastic Member Clamps. The application is incorporated-by-reference herein in its entirety.

FIELD OF THE INVENTION

The present application is generally directed to orthopedic stabilization systems, and in particular, to systems including clamps and rod members.

BACKGROUND

Many types of spinal irregularities cause pain, limit range of motion, or injure the nervous system within the spinal column. These irregularities can result from, without limitations, trauma, tumor, disc degeneration, and disease. Often, these irregularities are treated by immobilizing a portion of the spine. This treatment typically involves affixing a plurality of screws, hooks and/or clamps to one or more vertebrae and connecting the screws, hooks and/or clamps to an elongate rod that stabilizes members of the spine.

Accordingly, there is a need for improved systems involving screws, hooks and/or clamps for spinal stabilization.

SUMMARY OF THE INVENTION

Various systems, devices and methods related to spinal clamps are provided. In some embodiments, a spinal system comprises a clamp for receiving an elongate rod therein, wherein the clamp comprises an inner opening for receiving the elongate rod, a first opening in communication with the inner opening, and a second opening in communication with the inner opening; a set screw received in the first opening of the clamp; a bushing positioned at a distal end of the set screw; and an elastic member received in the second opening of the clamp, wherein the elastic member is configured to be in contact with the elongate rod received in the clamp.

In other embodiments, a spinal system comprises a clamp for receiving an elongate rod therein, wherein the clamp comprises an inner opening for receiving the elongate rod, a first opening in communication with the inner opening, and a second opening in communication with the inner opening, wherein the inner opening includes a groove for receiving an elastic member therein; a set screw received in the first opening of the clamp; and an elastic member received in the second opening of the clamp, wherein the elastic member is configured to be in contact with the elongate rod received in the clamp.

In other embodiments, a spinal system comprises a clamp for receiving an elongate rod therein, wherein the clamp comprises an inner opening for receiving the elongate rod, a first opening in communication with the inner opening, and a second opening in communication with the inner opening; a set screw received in the first opening of the clamp; a bushing in contact with a distal end of the set screw, wherein the set screw includes a protrusion that extends past a portion of the bushing; and an elastic member received in the second opening of the clamp, wherein the elastic member is configured to be in contact with the elongate rod received in the clamp.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a top perspective view of an in-line clamp according to some embodiments.

FIG. 1B is a side cross-sectional view of the in-line clamp in FIG. 1A.

FIG. 2A is a side cross-sectional view of an alternative in-line clamp according to some embodiments.

FIG. 2B is a top perspective view of the in-line clamp in FIG. 2A.

FIG. 2C is a side cross-sectional view of the in-line clamp in FIG. 2A.

FIG. 3A is a side cross-sectional view of an alternative in-line clamp according to some embodiments.

FIG. 3B is a top perspective view of the clamp in FIG. 3A.

FIG. 4A is a top perspective view of an off-set clamp according to some embodiments.

FIG. 4B is a cross-sectional view of the off-set clamp in FIG. 4A.

FIG. 4C is a top perspective view of the off-set clamp in FIG. 4A with an elastic member.

FIG. 4D is a cross-sectional view of the off-set clamp in FIG. 4A with an elastic member.

FIG. 5A is a top perspective view of a tulip clamp according to some embodiments.

FIG. 5B is a side cross-sectional view of the tulip clamp in FIG. 5A.

FIG. 6 is a top perspective view of an integrated holder and tensioner instrument according to some embodiments.

FIG. 7 is a front cross-sectional view of the integrated holder and tensioner instrument of FIG. 6.

FIG. 8 is a close-up view of a distal portion of the integrated holder and tensioner instrument of FIG. 6.

FIG. 9 is an alternate close-up view of a distal portion of the integrated holder and tensioner instrument of FIG. 6.

FIG. 10 is a close-up view of a proximal portion of the integrated holder and tensioner instrument of FIG. 6.

FIG. 11 is a close-up view of a distal portion of an alternate integrated holder and tensioner instrument according to some embodiments.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

The present disclosure relates to spinal stabilization devices, and in particular, clamps that utilize elastic members to grasp onto bone. The various clamps can be placed in many positions relative to a bone member, such as in-line or off-set.

Many spinal components exist to assist in stabilizing spinal members. Among the components that are used are spinal hooks, which can grasp onto bone. While spinal hooks are effective and can be less disruptive and prone to causing injury compared to other components, such as screws, there is a possibility of the hooks disengaging post surgery, therefore leading to potentially additional surgical intervention to rectify.

The present application is directed to spinal stabilization devices that overcome challenges associated with current spinal devices. In particular, it has been found that spinal clamps can be effectively provided that use elastic members, such as elastic bands, to grasp onto bone members. The use of the elastic members advantageously secures the clamps to bone, and reduces the risk of the devices being inadvertently removed from the bone post-surgery.

FIGS. 1A-1C illustrate different views of an in-line clamp utilizing an elastic member, according to some embodi-

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ments. The in-line clamp 10 comprises a body 12 for receiving a rod member 80 therein. The in-line clamp 10 is configured to receive an elastic member 60 therethrough to secure the clamp 10 to a bone member (e.g., a vertebral body).

The in-line clamp 10 includes a body 12 that forms a curved opening or mouth 17 for receiving a rod member 80 therein. As shown in FIG. 1A, in some embodiments, the curved opening 17 of the body 12 is formed facing downwardly over the rod member 80, such that the rod member 80 is bottom-loaded relative to the clamp 10. Advantageously, the curved opening 17 is also configured to receive a portion of the elastic member 60, which wraps around a vertebral body or bone member. As shown in FIG. 1A, the elastic member 60 can be positioned such that a first portion of the elastic member 60 is in contact with a first side of the rod member 80 and a second portion of the elastic member 60 is in contact with a second side of the rod member 80 opposite from the first side after looping the elastic member around a bone member. In other embodiments, such as shown in FIG. 2A, the elastic member 60 can be configured such that portions of the elastic member 60 remain pressed between one-side of the rod member 80 and an inner wall of the clamp 10, even after looping the elastic member 60 around a bone member. One skilled in the art will appreciate that the positioning of the elastic member 60 relative to the rod member 80 and the clamp 10 can vary, and that the illustrations shown herein are not meant to limit the positions available for placing the elastic member, but rather show options for placing the elastic member in the system.

The curved opening 17 for receiving the rod member 80 is formed by inner walls of the clamp 10. In some embodiments, the curved opening 17 has a radius that can accommodate both the rod 80 and the elongate member 60 placed therein. As shown in FIG. 1B, the inner walls of the clamp 10 can include a track or groove 32 formed therein that runs along the inner walls of the clamp 10. The groove 32 advantageously accommodates the elastic member 32 therein. In some embodiments, the groove 32 has a width that is approximately the same as the width of an elastic member 60 positioned therein. With the addition of the groove 32, the clamp 10, rod member 80 and elastic member 60 can be held together, even before tightening the set screw 25 (as discussed below). In some embodiments, the groove 32 runs substantially or completely along the inner walls of the clamp 10.

The curved opening 17 is in communication with a first opening 14 and a second opening 16, each of which extends through the body 12 of the clamp 10. The first opening 14, which runs diagonally relative to a vertical mid-plane of the device, is configured to receive a threaded set screw 25 therein. When the rod member 80 and elastic member 60 have been placed in a desired position within the mouth of the clamp 10, the set screw 25 can be downwardly threaded to apply a compression force on the rod member 80 and elastic member 60 to securely capture the members within the clamp 10.

In some embodiments, a separate bushing 28 can be attached to a distal end of the set screw 25, as shown in FIGS. 1A and 1B. The bushing 28 advantageously provides an intermediary contact surface between the set screw 25 and the elastic member 60, thereby preventing the elastic member 60 from fraying or tearing from the contacting surface of the set screw 25. As shown in FIG. 1B, the bushing 28 has a curved contact surface 29 that conforms to the shape of the rod member 80 and elastic member 60 positioned in the mouth of the clamp. The curved contact

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surface 29 advantageously serves as a pressure distribution surface that comfortably distributes pressure around the rod and elastic member 60 as the threaded set screw 25 is downwardly threaded. In other embodiments, the contact surface 29 of the bushing 28 is partially straight. While the set screw 25 and bushing 28 are illustrated as separate components, in other embodiments, the two components are integrated components. The set screw 25 and bushing 28 can be molded together, or can be formed of a monolithic member. In some embodiments, the set screw 25 and the bushing 28 are formed of different materials, while in other embodiments, the set screw 25 and the bushing 28 are formed of the same materials. In some embodiments, the set screw 25 and/or bushing 28 can be formed of different biocompatible metals, such as stainless steel, titanium or cobalt-chrome.

The second opening 16, which runs generally through a vertical mid-plane of the device, is configured to receive one or more elastic members 60 therethrough. As shown in FIG. 1A, this central opening 16 is wide enough to receive two ends or portions of an elastic member 60 that has been looped around a vertebral body. One skilled in the art will appreciate that the positioning of the first and second openings 14 and 16 should not be limited. For example, in alternative embodiments, the positions of the first opening 14 and the second opening 16 can be switched. Alternatively, in other embodiments, the second opening 16 for receiving the ends of the elastic members 60 can be moved away from the vertical mid-plane of the device.

In some embodiments, the elastic member 60 can be a cable. Preferably, the elastic member 60 is a wide elastic band 60. The use of a wide elastic band 60 can advantageously reduce the risk of damage to tissue lacerations or injury. In some embodiments, the elastic band 60 is between 2 and 8 mm, or greater than 4 mm. In some embodiments, the band is composed of a polymer, such as PET. To ensure that the clamp 10 remains secured to a bone member via the elastic band 60, a tensioner can be included as part of the system to make sure that the bands are in proper tension and tightness.

The in-line clamp 10 can be used as follows. In some embodiments, the elastic member 60 (e.g., band) can first be introduced to the clamp 10 without the rod 80 inserted therein. The elastic member 60 can be positioned along and within the single groove 32 that extends along an inner surface of the clamp, which advantageously helps to center the elastic member 60. Both ends of the elastic member 60 can extend through the second hole 16, thereby forming a loop at the bottom of the elastic member 60. The loop of the elastic member 60 can be wrapped around a portion of a spine (not shown), such as a lamina. With the elastic member 60 in place, a rod member 80 can be received through the bottom opening 17 of the clamp 10. Once the rod member 80 is pushed through the bottom opening 17 of the clamp 10 and against the inner walls of the clamp, the rod member 80 is provisionally held in the clamp 10. At this time, the rod member 80 is advantageously free to translate along the direction of its longitudinal axis.

With the rod member 80 in the clamp, a tensioner can be used to tension the elastic member 60, thereby pulling the spine to the rod member 80 in order to correct a deformity. When adequate correction is obtained, the set screw 25 can be downwardly threaded to tighten and securely capture the elastic member 60 and rod member 80. The bushing 28, which serves as either a floating piece that is separate from the set screw 25 or an integrally formed piece with the set screw 25, is positioned at the distal end of the set screw 25

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to distribute the tightening load of the set screw 25 uniformly across the elastic member 60 and the rod member 80. As the set screw 25 is downwardly threaded, the set screw 25 compresses against the elastic member 60 and rod member 80, thereby securing the system. At this time, the rod member 80 is locked in place and is no longer free to

translate. FIGS. 2A-2C illustrate different views of an alternate in-line clamp 10 according to some embodiments. The in-line clamp 10 in these figures differs from the clamp in FIGS. 1A and 1B in that it has a first opening 14, a second opening 16 and an additional third opening 18 that extends through the body of the clamp. As shown best in FIG. 2A, the additional third opening 18 is configured to receive two portions or strands of a looped elastic member 60, which also extend into the second opening 16. In addition, while the curved opening 17 opens downward such that the rod member 80 remains bottom-loaded, the curved opening 17 is now more diametrically positioned relative to a vertical mid-plane of the device.

In this embodiment, the elastic member 60 passes through both the second opening 16 and the third opening 18. A loop is formed by the elastic member 60 closer to the third opening 18 and is capable of wrapping around a bone member. In the present embodiments, when a rod member 80 is positioned in the curved opening 17 of the clamp 10, the elastic member 60 is kept on one side of the rod member 80. In other words, the elastic member 60 is positioned between the rod member 80 and the inner walls of the clamp 10, as shown in FIG. 2A. The addition of the third opening 18 thus provides additional ways to accommodate the elastic member 60 relative to the rod member 80 and the clamp 10.

FIGS. 3A and 3B illustrate different views of an alternative in-line clamp 10 according to some embodiments. The in-line clamp 10 in these figures differs from the clamp in FIGS. 1A and 1B in that it has a first opening 14, a second opening 16, additional third and fourth openings 18, 19, and a unique set screw 25 having an extension member 26. Both the third opening 18 and the fourth opening 19 are in communication with the opening 17 for receiving a rod member, and are positioned near a lower portion of the clamp 10.

The clamp 10 is configured to receive an elastic member 60 therethrough. In some embodiments, a first end of the elastic member 60 can extend through the third opening 18 while a second end of the elastic member 60 can extend through the fourth opening 19, such that both the first and second ends of the elastic member 60 meet and pass through the second opening 16. A loop is formed at the bottom of the elastic member 60 to receive a bone member. In alternate embodiments, a first end of the elastic member 60 and a second end of the elastic member 60 can pass through the third opening 18 and through the second opening 16 (similar to as shown in FIG. 2A). In yet further alternate embodiments, a first end of the elastic member 60 and a second end of the elastic member 60 can pass through the fourth opening 19 and through the second opening 16. With the latter two options, the elastic member 60 can be kept to generally one side of a rod member 80 inserted into the clamp 10. Accordingly, with the addition of the third opening 14 and the fourth opening 19, this advantageously provides a number of different options for securing the clamp to bone.

The clamp 10 includes a unique set screw 25 having an extension member 26 formed on a distal end thereof. As shown in FIG. 3A, the extension member 26 is a shaped protrusion that can extend through the bushing 28. When the elastic member 60 passes along the inner walls near the

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bushing 28 (e.g., while entering or exiting the fourth opening 19), the extension member 26 of the set screw 25 is advantageously configured to contact a portion of the elastic member 60 positioned therein. This additional contact provided by the extension member 26 of the set screw 25 helps to advantageously stabilize the elastic member 60 and, along with the bushing 28, helps to distribute the compressive load that occurs during downward threading of the screw 25. In some embodiments, the extension member 26 comprises a blunt tip to reduce the likelihood of fraying of the elastic member 60.

FIGS. 4A-4D illustrate different views of an off-set clamp according to some embodiments. The off-set clamp 100 is configured to receive an elastic member 60 (e.g., through slot or opening 116) on one side of the clamp 100, and a rod member 80 on an opposite side of the clamp 100. The clamp 100 comprises an upper plate 110 having a first opening 114 and a second opening 116 and a lower plate 120. The first opening 114 is configured to receive a set screw 125 that extends through the upper plate 110 and the lower plate 120. The second opening 116 is configured to receive an elastic member 60 as discussed below.

As shown in FIG. 4B, the upper plate 110 can be physically separated and lifted away from the lower plate 120, thereby providing a space 130 for receiving one or more portions of an elastic member 60 therethrough. In some embodiments, the upper plate 110 can translate both vertically and rotationally relative to the lower plate 120, thereby providing a large enough space 130 (shown in FIG. 4B) for receiving an elastic member 60. The elastic member 60 can form a loop that extends around a bone member, with a first portion of the elastic member 60 in contact with a first lower surface 121 of the lower plate 120 and a second portion of the elastic member 60 in contact with a second lower surface (not shown) on the opposite side of the lower plate 120. The elastic member's trajectory is shown in FIGS. 4C and 4D. In some embodiments, the lower surfaces 121 of the lower plate 120 can comprise an overhang for receiving the elastic member 60 to prevent the elastic member from sliding off of the assembly. With the portions of the elastic member 60 in contact with the lower portions of the lower plate 120, first and second ends of the elastic member 60 can be inserted through the space 130 (shown in FIG. 4B) created when the upper plate 110 is separated from the lower plate 120. The first and second ends of the elastic member 60 can then be inserted through the slot 116 formed in the upper plate 110.

With the elastic member 60 in place such that it is looped around a bone member and such that both of its ends pass through the slot 116, the upper plate 110 can be brought downwardly onto the lower plate 120, thereby securing the elastic member 60 therein. To ensure that the upper plate 110 is secure to the lower plate 120, the set screw 125 can be downwardly threaded, thereby compressively bringing the upper plate 110 into a secure relationship with the lower plate 120. Advantageously, the downward threading of the set screw 125 will also secure a rod member 80 received in the rod opening 117 formed on the opposite ends of the clamp 100. In other words, in some embodiments, the downward threading of the set screw 125 will both secure the elastic member 60 within the upper and lower plates on one side of the clamp 100, and simultaneously secure an off-set rod member 80 that is positioned in a rod opening 117 on an opposite side of the clamp 100.

When the upper plate 110 is removed from the lower plate 120 (e.g., vertically and/or rotationally) such that an elastic member 60 can be received in the space 130, the clamp 100 can be considered to be in an "open" or "unlocked" con-

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figuration. When the upper plate **110** is downwardly secured to the lower plate **120** (e.g., via the set screw **125**) such that the elastic member **60** is secured within the upper plate **110** and the lower plate **120**, the clamp **100** can be considered to be in a “closed” or “locked” configuration.

The off-set clamp **100** can be used as follows. When the clamp is ready to receive the elastic member **60** and rod member **80**, the upper plate **110** can be raised and rotated slightly from the lower plate **120** to provide room (e.g., space **130**) for inserting an elastic member (e.g., band) **60** between the upper plate **110** and the lower plate **120**. The elastic member can wrap around a spinal portion (e.g., a lamina), and can extend along the outer, bottom side walls **121** of the lower plate **120**. The bottom side walls **121** of the lower plate **120** can include an overhang to prevent the elastic member **60** from sliding off the clamp **100**. Both ends of the elastic member **60** can continue to extend through the slot **116** formed in the upper plate **110**. On the opposite side of the clamp **100**, a rod member **80** can be received between the upper plate **110** and the lower plate **120**. Before tightening the set screw **125** that extends between the upper plate **110** and the lower plate **120**, the rod member **80** is provisionally held in the clamp **100** and is advantageously free to translate along its longitudinal axis. With the elastic member **60** wrapped around a bone member and the clamp **100**, and the rod member **80** received on the opposite end, the set screw **125** can be tightened such that the clamp **100** clamps down on both the elastic member **60** and rod member **80**. This advantageously secures both the elastic member **60** between the upper plate **110** and lower plate **120** on one side of the clamp **100**, and the off-set rod member **80** within the rod opening **117** on the opposite side of the clamp **100**.

FIGS. 5A and 5B illustrate different views of a tulip clamp according to some embodiments. The tulip clamp **200** comprises a first arm **202** and an opposing second arm **204** that join at a base, thereby forming a U-shaped channel for receiving a rod member **80**. The first arm **202** comprises a first angled slot or opening **214** for receiving a first end of an elastic member **60** therethrough and the second arm **204** comprises a second angled slot or opening **216** for receiving a second end of the elastic member **60** therethrough. The bottom of the elastic member **60** can form a loop that passes through a third opening **218** formed at the base of the tulip clamp. The loop is capable of looping around a bone member, such as a lamina.

Advantageously, as shown in FIG. 5B, the third opening **218** of the tulip clamp **200** has slanted inner walls. These inner walls advantageously serve as a guide for first and second portions of the elastic member **60** prior to the elastic member **60** opening into a loop below the clamp **200**. In some embodiments, the third opening **218** has a width that is greater than a maximum width of the first opening **214** and/or the second opening **216**.

The tulip clamp **200** can be used as follows. An elastic member **60** can first be inserted through the tulip clamp **200** by passing first and second ends of the elastic member **60** through the base opening **218**. The first end of the elastic member **60** can pass through the angled slot or opening **214**, while the second of the elastic member **60** can pass through the angled slot or opening **216**. The bottom of the elastic member **60** forms a loop that can be wrapped around a spinal portion, such as a lamina. With the elastic member **60** in place, a rod member **80** can be introduced into the U-shaped channel of the tulip head, such that the elastic member **60** contacts the rod member **80** on two sides. After the rod member **80** is delivered downwardly into the tulip head, a locking cap including a set screw (not shown) can be

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delivered onto the rod member **80**. In some embodiments, the locking cap can rest in locking cap slots **231** found in the arms. In some embodiments, the set screw is threaded and interacts with threads on the arms of the tulip clamp. In other embodiments, in lieu of a set screw and locking cap, a single non-threaded locking cap can be provided. Prior to locking the set screw, the rod member **80** can be provisionally captured such that it is advantageously free to move along its longitudinal axis. With the elastic member **60** and rod member **80** in place, a tensioner can tension the band to pull the spine up to the rod member **80** to correct a deformity. Once the deformity is corrected by tensioning the band, the set screw in the locking cap can be downwardly tightened to secure the rod member **80** and elastic member **60** within the tulip clamp **200**.

The clamps discussed above can be accompanied by one or more instruments to facilitate insertion and implantation. For example, in order to properly install a clamp, a tensioner may be used to help tension the elastic member while it is wrapped around a bony structure. The tensioner can hold the elastic member in a corrected position until the set screw of the clamp is finally tightened to securely hold the construct. Accordingly, the clamps can be accompanied by at least two instruments—a holder instrument to facilitate insertion and delivery of the clamp, and a tensioner instrument to hold the elastic band in tension prior to securing the construct.

Alternatively, a novel integrated holder and tensioner instrument can be provided to facilitate insertion and implantation of a clamping assembly. FIG. 6 is a top perspective view of an integrated holder and tensioner instrument according to some embodiments. By providing an integrated holder and tensioner, the instrument advantageously reduces the need for multiple instruments, and provides a secure means for installing the clamp and elastic member assembly securely.

As shown in FIG. 6, the integrated holder and tensioner instrument **300** comprises a distal portion comprising a clamp holder **310** for holding a clamp. The clamp holder **310** is operatively connected to an outer sleeve **320** which includes one or more slots **322** through which an elastic member can pass therethrough. Adjacent to a proximal portion of the outer sleeve **320** is an elastic member lock base **340** and an elastic member lock **330**, the latter of which is also designed to receive an elastic member therethrough. The integrated instrument **300** further includes a tensioner driver **350** for tensioning an elastic member and a clamp holder handle **300** for opening and closing the clamp holder **310**. Each of these components is discussed in greater detail below.

In some embodiments, a distal portion of the instrument **300** comprises a clamp holder **310** for receiving a clamp therein. The clamp holder **310** comprises a pair of fingers or tips **312** that can flex open to receive a clamp therein. The tips **312** are capable of flexing via flexible slits or cuts **314**, as shown in FIG. 7. The clamp holder **310** can have two configurations: an “open” configuration, whereby it is capable of provisionally and gently holding a clamp therein, and a “closed” configuration, whereby it grips the clamp therein securely and tightly. The clamp holder **310** can be in the open configuration when it first grasps a clamp **10** therein. Once the clamp **10** is provisionally captured in the clamp holder **310**, the clamp holder **310** can be placed in a closed configuration to tighten the grip on the clamp **10**. This can be accomplished by rotating the clamp holder handle **360**, which causes the outer sleeve **320** to translate downwardly onto the clamp holder **310**, thereby preventing the tips **312** of the clamp holder **310** from flexing open.

The outer sleeve **320** comprises an elongate body that is operably attached to the clamp holder **310**. A distal portion of the outer sleeve **320** is configured to include a pair of elongated slots **322**. The elongated slots **320** are configured to receive the ends of the elastic member after the elastic member has been passed through the clamp (as shown in FIG. 1A) and into the distal end of the outer sleeve **320**. Each end of the elastic member can pass through a slot **320** formed in the outer sleeve and can extend along the length of the outer sleeve, whereby they can be received in the elastic member locks **330**.

The elastic member locks **330** comprise a pair of “wing” shaped members designed to receive an elastic member therein. In some embodiments, each of the elastic member locks **330** comprises an opening or slit **332** for receiving and capturing an end of the elastic member. As the elastic member passes through an elastic member lock **330**, the elastic member lock **330** captures and secures the elastic member via a one-way, unidirectional auto-tightening mechanism, thereby preventing the elastic member from backing out from the elastic member lock **330**. In other words, an elastic member that passes through the elastic member lock **330** can be pulled in tension, without worrying about backing out of the elastic member. The one-way, auto-tightening mechanism can comprise different types of mechanisms, including cam, grooved, flat, and/or rounded surfaces whereby once engaged, they prevent sliding of the elastic member within the lock **330**. When desired, an elastic member can be released from an elastic member lock **330** by pressing the elastic member lock **330** downwardly, thereby actuating a release function.

The elastic member locks **330** are positioned adjacent to the elastic member lock base **340** and the tensioner driver **350**, which work in conjunction to place the ends of the elastic member in tension. By rotating the tensioner driver **350**, this causes the elastic member lock base **340** to translate along the longitudinal axis of the outer sleeve in a proximal direction away from the clamp **10**. This movement of the elastic member lock base **340** pulls on the elastic member, thereby placing the ends of the elastic member (which are constrained to the elastic member locks **330**) in greater tension.

In addition to these features, the integrated instrument **300** includes a clamp holder handle **360** positioned at a proximal portion of the instrument **300**. As discussed earlier, the clamp holder handle **360** is capable of actuating the outer sleeve **320**, thereby causing the clamp holder **310** to be in an “open” or “closed” position.

Methods for using the integrated holder and tensioning instrument **300** are now described. In some embodiments, a surgeon would select a clamp **10** to be inserted into a patient. The surgeon can then engage the instrument **300** to the clamp **10** via the clamp holder **310**. The clamp holder **310** is in an “open” configuration, and is only provisionally engaged with the clamp **300**. After provisionally engaging the clamp holder **310** to the clamp **10**, an elastic member (e.g., a band) can be passed through the clamp **10** and out through the clamp holder **310** and the slots **322** of the outer sleeve **320**. In addition to retaining the clamp **10**, the clamp holder **310** can be used to provisionally retain a rod member that is forced into the clamp **10**. With the rod and elastic member provisionally retained within the clamp **10** and clamp holder **310**, the surgeon can rotate the clamp holder handle **360** to place the clamp holder **310** in a “locked” configuration, thereby tightening the grip on the clamp **10**.

At this time, the ends of the elastic member can be passed through the elastic member locks **330**, thereby securely

capturing the ends. Once the ends of the elastic member are captured in the elastic member locks **330**, the tensioner driver **350** can be rotated to place further tension on the elastic member's ends. Once the elastic member has been placed in a desired amount of tension, the surgeon can use a hex driver to tighten the set screw **25** of the clamp **10** to thereby secure the clamp member, rod member and elastic member. As the clamp **10** and its associated elastic member are now assembled, the surgeon can either (i) unlock the elastic member locks **330** to slide the elastic member ends out or (ii) cut the elastic member on either side without unlocking the elastic member locks. The clamp holder **360** can then be rotated to disengage the instrument **300** from the installed clamp **10**, thereby allowing the instrument **300** to be removed from the assembled clamp construct in the patient. Optionally, as the ends of the elastic member are loose, the surgeon may choose to cauterize the ends to prevent fraying of the loose ends.

In addition to the components discussed above, the integrated holder and tensioner instrument **300** can further include other components. In some embodiments, the tensioner instrument **300** can be accompanied by a counter torque device (not shown) that can be attached to the counter torque attachment surface **370** on the elastic member base **340**. The counter torque device helps to limit rotation to only those component necessary when rotating the tensioner driver. In addition, the tensioner instrument **300** can also be accompanied by a secondary handle that attaches to the clamp handle **360** to limit or indicate the amount of torque being applied, thereby advantageously preventing over-tensioning of the elastic member.

FIG. 7 is a front cross-sectional view of the integrated holder and tensioner instrument of FIG. 6. From this view, one can see the cross-section of the clamp holder **310**, including the flexible cuts or slits **314** that enable flexion of the clamp holder tips **312**.

FIG. 8 is a close-up view of a distal portion of the integrated holder and tensioner instrument of FIG. 6. From this view, one can see the upper opening **16** in the clamp **10** through which the ends of the elastic member can pass before passing through the slots **322** in the outer sleeve **320**.

FIG. 9 is an alternate close-up view of a distal portion of the integrated holder and tensioner instrument of FIG. 6. From this view, one can see a rod member **80** that is provisionally captured in the clamp **10** via the clamp holder **310**. To tighten the grip on the rod member **80** and clamp **10**, the outer sleeve **320** can be translated downwardly to compress the flexible tips of the clamp holder **310**, thereby causing the clamp holder **310** to be in a “closed” tight position.

FIG. 10 is a close-up view of a proximal portion of the integrated holder and tensioner instrument of FIG. 6. From this view, one can see the opening or slit **332** formed in each of the elastic member locks **330**, through which an elastic member can pass through. The slit **332** serves as a contact or locking surface of the elastic member, which is configured to pass through each of the elastic member locks **330** prior to tensioning the elastic member.

An alternate design of an integrated holder and tensioner instrument is now described. FIG. 11 is a close-up view of a distal portion of an alternate integrated holder and tensioner instrument according to some embodiments. The instrument in FIG. 11 shares many features with the instrument in FIG. 6, including a clamp holder, an outer sleeve, elastic member locks, an elastic member base, a tensioner driver, and a clamp holder handle. However, in contrast to the instrument in FIG. 6, the instrument in FIG. 11 com-

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prises a clamp holder **310** having a pair of hinged tips **312**. The hinges **317** allow the tips **312** to open and close on a clamp and/or rod member similarly to the instrument in FIG. 6. In further contrast to the instrument in FIG. 6, the instrument in FIG. 11 can also include one or more teeth for

securing the clamp holder **310** to the outer sleeve **310**. It will be apparent to those skilled in the art that various modifications and variations can be made in the present invention without departing from the scope or spirit of the invention. Moreover, the improved bone screw assemblies and related methods of use need not feature all of the objects, advantages, features and aspects discussed above. Thus, for example, those skilled in the art will recognize that the invention can be embodied or carried out in a manner that achieves or optimizes one advantage or a group of advantages as taught herein without necessarily achieving other objects or advantages as may be taught or suggested herein. In addition, while a number of variations of the invention have been shown and described in detail, other modifications and methods of use, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is contemplated that various combinations or subcombinations of these specific features and aspects of embodiments may be made and still fall within the scope of the invention. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the discussed bone screw assemblies. Thus, it is intended that the present invention cover the modifications and variations of this invention provided that they come within the scope of the appended claims or their equivalents.

What is claimed is:

1. A surgical system comprising:
 - a clamp receiving a rod and an elastic member therein, wherein the elastic member extends around a portion of the rod and is configured to wrap around a bone member, wherein the clamp comprises a first lower opening, a second lower opening and an upper opening, wherein a first end of the elastic member passes through the first lower opening and a second end of the elastic member passes through the second lower opening such that both the first end and the second end of the elastic member can pass through the upper opening,
 - an instrument configured to hold the clamp and tension the elastic member, the instrument comprising a clamp holder with tips for grasping the clamp and a tensioner driver for increasing tension on the elastic member, wherein the clamp further comprises a set screw opening, wherein a set screw is received in the set screw opening, and the set screw engages the elastic member when the set screw is positioned through the set screw opening, and wherein the upper opening is located between the first lower opening and the set screw opening and the set screw opening is located between the upper opening and the second lower opening.
2. The system of claim 1, wherein the clamp further comprises an inner opening formed by an inner curved wall of the clamp, wherein the inner curved wall includes a groove for receiving the elastic member.
3. The system of claim 1, wherein the instrument further comprises an outer sleeve operably attached to the clamp holder.
4. The system of claim 3, wherein the outer sleeve comprises a pair of slots through which the elastic member of the clamp can pass therethrough.

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5. The system of claim 1, wherein the instrument further comprises an elastic member lock for receiving a portion of the elastic member therein.

6. The system of claim 1, wherein the instrument includes an outer sleeve having elongate slots at a distal end, and the elastic member passes through the slots when the instrument is holding the clamp.

7. A surgical system comprising:

a clamp receiving a bushing and a set screw therein, wherein the clamp further receives a rod member and an elastic member, wherein the elastic member extends around a portion of the rod member, wherein the clamp comprises a first lower opening, a second lower opening and an upper opening, wherein a first end of the elastic member passes through the first lower opening and a second end of the elastic member passes through the second lower opening such that both the first end and the second end of the elastic member can pass through the upper opening, wherein the clamp further comprises a set screw opening and wherein a set screw is received in the set screw opening, wherein the upper opening is located between the first lower opening and the set screw opening and the set screw opening is located between the upper opening and the second lower opening, and

an instrument configured to hold the clamp, wherein the instrument comprises an outer sleeve and a clamp holder for grasping the clamp, the clamp holder operatively connected to the outer sleeve, wherein the clamp holder comprises flexible tips, and the outer sleeve includes elongate slots at a distal end, wherein the elastic member passes through the slots when the instrument is holding the clamp.

8. The system of claim 7, wherein the flexible tips of the clamp holder are flexible due to flexible cuts.

9. The system of claim 7, wherein the flexible tips of the clamp holder are flexible due to hinges.

10. The system of claim 7, wherein the instrument is configured to apply tension to the elongate member while holding the clamp.

11. The system of claim 10, wherein the instrument comprises a tensioner driver for applying tension to the elastic member while the elastic member is held by one or more elastic member locks.

12. The system of claim 11, wherein the one or more elastic member locks are in the shape of wings with a slit formed therein.

13. The system of claim 7, wherein the instrument further comprises a clamp holder handle for placing the flexible tips in either an open or closed configuration, wherein in the closed configuration the clamp holder has a greater grip on the clamp than in the open configuration.

14. A surgical system comprising:

a clamp receiving a rod member and an elastic member, wherein the elastic member extends around a portion of the rod member, wherein the clamp comprises a first lower opening, a second lower opening and an upper opening, wherein a first end of the elastic member passes through the first lower opening and a second end of the elastic member passes through the second lower opening such that both the first end and the second end of the elastic member can pass through the upper opening, and

an instrument configured to hold the clamp, wherein the instrument comprises a clamp holder for grasping the clamp and a tensioner driver for tensioning the elastic member,

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wherein the clamp further comprises a set screw opening,
wherein a set screw is received in the set screw opening,
and the set screw engages the elastic member when the
set screw is positioned through the set screw opening,
and

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wherein the upper opening is located between the first
lower opening and the set screw opening and the set
screw opening is located between the upper opening
and the second lower opening.

15. The system of claim **14**, wherein the instrument 10
comprises an outer sleeve operably attached to the clamp
holder, wherein the outer sleeve is capable of axial transla-
tion along a longitudinal length of the instrument.

16. The system of claim **15**, wherein the outer sleeve is
actuated by a clamp holder handle.

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17. The system of claim **14**, wherein the tensioner driver
works in conjunction with an elastic member base to
increase tension on the elastic member.

18. The system of claim **14**, wherein the instrument
further comprises a pair of elastic member locks for receiv- 20
ing different ends of the elastic member.

19. The system of claim **18**, wherein the elastic member
locks each comprise an opening for receiving a portion of
the elastic member therethrough.

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